

REMARKS

The present communication responds to the Office Action of October 19, 2006. In it, claims 1-2 and 5-22 were rejected, and claim 2 objected to.

In this response, claims 2 and 18 have been amended to clarify the cannula cover.

Claims 23 and 24 have been added.

It is submitted that the claim amendments and claim additions do not add new matter.

Reconsideration is requested.

Rejection under 35 U.S.C. § 102

Claims 1, 5-6 and 18-21 were rejected under 35 U.S.C. § 102(b) over Nathan et al. (5,384,255).

Claims 1, 5-10, 12, 15-18 and 22 were rejected under 35 U.S.C. § 102(b) over Castillo et al. (5,336,199).

The § 102(b) rejections are improper for at least the following reasons.

§ 102(b) rejection over Nathan

Nathan discloses a needle cover assembly for covering needle 110 where “the needle cover assembly 102 can be constructed out of four pieces: a frustum shaped base member 112, see Fig. 12; an elongated cover member which has a first half 160 and an opposite unequal second half 162; and a rotatable collar member or actuator enclosure 120.” *Castillo, col. 9, lines 24-29.*

As can be seen in Fig. 10, collar member 120 is positioned at a distal end of the needle 110 relative to the needle tip 111. When cover member halves 160 and 162 are moved from the closed to the open position of Fig. 10, needle 110 is exposed immediately. This is because collar member 120 does not cover the needle 110 and thus is not a needle cover. Rather, collar member 120 covers partially the frustum shaped base member 112 from which needle 110 extends.

Therefore, Nathan does not disclose a “cannula cover for an injector” as recited by independent claims 1 and 18.

Because collar member 120 is not a needle cover, its rotational movement down frustum shaped base member 112 does not cause the needle to be exposed from it. Rather, rotational movement of collar member 120 causes elongated cover member halves 160 and 162 to separate, thereby exposing needle 110 from cover member halves. As a result, Nathan does not disclose that a cannula cover “can be axially retracted prior to injection to expose a cannula and the cannula cover exhibits a substantially closed front facing side comprising a cannula passage”, from independent claims 1 and 18.

Furthermore, as can be seen from Figs. 14 and 10, needle cover assembly 102 has a closed and an open position. In its closed position (Fig. 14) needle 110 is not exposed to an opening, i.e. spiral shaped channels 140, or exposed from cover member halves 160, 162. In its open position (Fig. 10) needle 110 is exposed to spiral shaped channels 140 and is exposed from cover member halves 160, 162. Whether needle cover assembly 102 is in its closed or open position, needle 110 is not exposed to a cannula passage opening prior to exposure of the cannula from the cannula cover. Therefore, Nathan does not disclose a cannula cover with an associated sealing device where “the sealing device expos[es] the cannula to the cannula passage opening via a radial movement of the sealing device away from the center of the cannula passage opening prior to exposure of the cannula from the cannula cover” from independent claim 1; or a cannula cover with a closure where “the movement of the closure comprising a portion of the closure moving in a radial movement away from the center of the cannula passage prior to exposure of the cannula from the cannula cover” from independent claim 18.

Nathan does not disclose each of the recitations of at least the independent claims and reconsideration and withdrawal of the § 102 rejection over Nathan are requested.

§ 102(b) rejection over Castillo

With respect to the medical needle and needle sheath assembly of Castillo, the Examiner is incorrect where he states:

a sealing device (26) is coupled to the interior of the device that can expose the cannula opening via radial retraction of the sealing device (Figure 4), wherein the sealing device (or strip) comprises a covering flap (26) that can be slid away in a longitudinal guide. *Office Action, page 3, last paragraph. (emphasis added)*

This is because in Castillo, movement of strip 26 *towards* opening 54 enables needle 14 to pass through it (*See Castillo, Fig. 4*), and

extending sheath sub-assembly (16) from its retracted condition causes needle (14) to be withdrawn from opening (54) in blocker element (26) thus permitting compressed spring member (52) to move element (26) to an extended position whereat its indicator portion (56) is projected outside the exterior cylindrical surface of sheath body (22). *Castillo, col. 4, lines 41-47. (See Castillo, Fig. 5)*

As a result, Castillo moves blocker element 26 radially *towards* a central needle axis in order to expose needle 14 to sheath sub-assembly 16 before the needle is exposed from sheath sub-assembly. Therefore, Castillo does not disclose that “the sealing device expos[es] the cannula to the cannula passage opening via a radial movement of the sealing device away from the center of the cannula passage opening prior to exposure of the cannula from the cannula cover” as provided in independent claim 1; or that “movement of the closure comprising a portion of the closure moving in a radial movement away from the center of the cannula passage [] expose[s] the cannula to the cannula passage prior to exposure of the cannula from the cannula cover” as provided in independent claim 18.

It is submitted that Castillo does not disclose each of the recitations of at least the independent claims, and reconsideration and withdrawal of the § 102 rejection over Castillo are requested.

Rejection under 35 U.S.C. § 103

Claim 2 was rejected under 35 U.S.C. § 103(a) over Nathan or Castillo in view of Vaillancourt (5,591,138).

Claims 13-14 were rejected under 35 U.S.C. § 103(a) over Nathan et al. (or Castillo et al) in view of Foster (6,217,559).

§ 103 rejection over Nathan or Castillo in view of Vaillancourt

Vaillancourt does not remedy the deficiencies of Nathan or Castillo for at least the following reasons. Vaillancourt discloses a protected needle assembly that includes sheath 17 and septum 18 for covering needle 15, and a projection 21. The sheath is coupled to a sleeve 20 having guide slot 22 that serves to guide projection 21 into positions corresponding to opened and closed sheath positions. *See Vaillancourt Figs 1-3*. The protected needle assembly in Vaillancourt, however, does not include a closure or sealing device that is capable of moving radially away from the center of the cannula passage, and such a closure is not suggested by the teachings of Vaillancourt. Accordingly, Vaillancourt does not disclose or suggest a “sealing device [that] expos[es] the cannula to the cannula passage opening via a radial movement of the sealing device away from the center of the cannula passage opening prior to exposure of the cannula from the cannula cover” from at least the independent claims 1 and 18. As a result, the combination of Vaillancourt with Nathan or Castillo would result in a needle cover or sheath as in Nathan or Castillo, but with the modification of the projection 21 extending from the needle cover from Vaillancourt. Therefore, one of ordinary skill in the art would not be motivated by Vaillancourt to modify Nathan or Castillo to include a sealing device movable radially away from the center of a cannula passage prior to exposing a needle from a needle cover, and the asserted combination is improper.

§ 103 rejection over Nathan or Castillo in view of Foster

Foster does not remedy the deficiencies of Nathan or Castillo for at least the following reasons. Foster discloses an automatic safety syringe with female sleeve member 40 that covers needle 24, the sleeve member 40 having an upper end where “a helical spring member 50 . . . having a lower end 51 which is fixedly secured to the upper end 42 of female sleeve member 40.” *Foster, col. 2, lines 30-33*. However, the safety syringe in Foster does not include a closure or sealing device for sealing a needle from the female sleeve member 40, the teaching of Foster does not suggest such a closure or sealing device, and Foster does not disclose or suggest the closure or sealing device from independent claims 1 and 18.

Furthermore, the Examiner is incorrect where he states “Foster teaches a threaded insert (50) that is coupled to the cover and control rotation movement (Figures 1-4, col 2, ln 1-69).

Rather, Foster discloses:

helical spring member 50 dimensioned to surround the male sleeve member 30 and having a lower end 51 which is fixedly secured to the upper end 42 of the female sleeve member 40 and has an upper end 52 which is fixedly secured to the underside of the traverse flange 23 of the syringe member. *Foster, col. 2, lines 31-35. (emphasis added)*

Nowhere in Foster does it disclose or suggest that helical spring 50 is or may be configured to serve as a threaded insert.

In view of the deficiencies of Foster that include, *inter alia*, the lack of a closure or sealing device and a threaded insert, the combination of Foster with Nathan or Castillo would result in a needle cover or sheath as in Nathan or Castillo, but with the modification of the spring 50 being coupled to the needle cover at a proximal end of the needle cover relative to an injection device. Therefore, one of ordinary skill in the art would not be motivated by Foster to modify Nathan or Castillo to include a sealing device movable radially away from the center of a cannula passage prior to exposing a needle from a needle cover, and the asserted combination is improper.

Vaillancourt or Foster, alone or in combination with Nathan or Castillo, do not disclose or suggest each of the recitations of at least the independent claims. Therefore, reconsideration and withdrawal of the § 103 rejections are requested.

New Claims

New claim 23 depends from claim 21, which is dependent on claim 18 and is therefore distinguishable over the cited art for at least the reasons set forth above.

New claim 24 is independent and includes recitations that are not disclosed or suggested in the cited references. Namely, new claim 24 includes the recitations of claim 1 and is thus distinguishable over the cited art for at least the reasons set forth above; and further new claim 24 recites that “the closed front facing side with cannula passage opening [is] positioned

proximate to the distal end of the cannula relative to the injector when the cannula cover is in a position prior to exposure of the cannula from the cannula cover.”

Dependent Claims

Dependent claims 2, 5-17, and 19-22 depend from their respective independent claims 1 and 18, and include further recitations. Therefore, claims 2, 5-17, and 19-22 are distinguishable over the cited art for at least the reasons set forth above.

Conclusion

A three month extension of time is requested, and the required fee should be charged to Deposit Account No. 04-1420. It is believed that no additional fees are due in connection with this paper, but the Office is authorized to charge any additional fees, including extension fees or other relief which may be required to Deposit Account No. 04-1420.

The application is in condition for allowance, and reconsideration and allowance are requested.

Respectfully submitted,

DORSEY & WHITNEY LLP
Customer Number 25763

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By:

David E. Bruhn
David E. Bruhn, Reg. No. 36,762
(612) 340-6317